

REMARKS

In the aforesaid Office Action, claims 1, 5, 9, and 23-29 were rejected under 35 USC §102(b) as being anticipated by or in the alternative under 35 USC §103(a) as being unpatentable over Verbeek (U.S. Patent No. 5,690,613), and claims 1, 16, 25, and 27-29 were rejected under 35 USC §102(b) as being anticipated by or in the alternative under 35 USC §103(a) as being unpatentable over Wantink (U.S. Patent No. 5,300,025), and claims 1-5, 9, 23-33, 35 and 37-39 were rejected under 35 USC §103(a) as being unpatentable over Verbeek in view of Samson et al. (U.S. Patent No. 5,782,811). Applicants note with appreciation the indication that claims 17-19 and 21 would be allowable if rewritten in independent form including all the limitations of the base and any intervening claims. Claims 1-41 are pending (new claims 40 and 41 being added by this amendment), and claims 6-8, 10-15, 20, 22, 34 and 36 are withdrawn from consideration.

The Examiner objected to claims 17-19 and 21 as being dependent from a rejected base claim. Applicants have added claim 41 corresponding to allowable claim 17.

The Examiner rejected claims 1, 5, 9, and 23-29 under 35 USC §102(b) as being anticipated by or in the alternative under 35 USC §103(a) as being unpatentable over Verbeek, stating that Verbeek discloses a balloon catheter having a proximal tubular member 50, a mandrel 30, a distal shaft section with inner and outer tubular members 70, 80, and a reinforcing member 13 formed of a first polymeric material. The Examiner states that according to Etherington & Roberts dictionary, Verbeek inherently teaches that the first polymeric material has a higher glass transition temperature (T_g) than the second

polymeric material forming the distal portion of the proximal tubular member due to the fact that the first polymeric material is used as a reinforcing structure and would be less flexible to provide support.

However, the reinforcing member 13 of Verbeek does not necessarily have a higher Tg than the second polymeric material forming the distal portion of the proximal tubular member, as required for an inherency rejection pursuant to MPEP 2112. The extrinsic evidence which the Examiner uses to show inherency is a dictionary definition of the Tg of adhesives, which appears to be based on a rubbery adhesive which is cooled from the rubber state until the adhesive becomes glassy below the Tg, i.e., "(Tg is) [t]hat temperature at which an adhesive loses its flexibility and becomes hard, inflexible and glasslike".

During a telephone conference with the Examiner on April 14, 2003, the Examiner indicated that he reads the Etherington & Roberts definition to mean that a harder material necessarily has a higher Tg than a softer material. Applicants have attached a definition of Tg for the Examiner's reference to clarify that the Tg is the temperature at which an amorphous polymer goes from its glassy state to its rubber state (i.e., as the polymer is heated to a temperature above the Tg), or vice versa (i.e., as the polymer is cooled to a temperature below the Tg). Thus, contrary to the Examiner's assumption, a higher Tg than the surrounding polymers is not an inherent characteristic of a polymer forming a reinforcing member, as discussed in more detail below.

The Examiner's reasoning does not reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior

art, as required for an inherency rejection. Specifically, reinforcing member 13 of Verbeek could still function as a reinforcing structure merely by increasing the wall thickness of the shaft, even if formed of a polymeric material having a lower Tg than the distal end of the proximal tubular member 50. Although Verbeek discloses that the reinforcing member 13 must be irradiated to prevent it from melting and thinning so that it is preserved as the inner tubular member 70 melts away, to provide a barrier for the pressure (see column 4, lines 25-30), reinforcing member 13 need not necessarily have a higher Tg than the distal end of the proximal tubular member 50 in order to provide a barrier for the pressure after inner tubular member 70 melts away (because a polymeric material which doesn't melt/thin as the inner tubular member 70 melts might nonetheless have a lower Tg than the proximal tubular member 50, and the addition of extra polymeric material including polymeric material having a lower Tg than the distal end of the proximal tubular member 50 would still "provide a barrier for the pressure" by increasing the wall thickness around the inflation lumen). Therefore, the Examiner has not established that the reinforcing member 13 disclosed in Verbeek must necessarily have a higher Tg than the distal portion of the proximal tubular member 70, and thus has not established inherency.

The Examiner rejected claims 1, 16, 25, and 27-29 under 35 USC §102(b) as being anticipated by or in the alternative under 35 USC §103(a) as being unpatentable over Wantink, stating that Wantink discloses a balloon catheter having a proximal tubular member 26 and a distal shaft section with inner and outer tubular members 16, 13, and a reinforcing member 28 formed of a first polymeric material. Similar to the rejection

based on Verbeek discussed above, the Examiner states that according to Etherington & Roberts dictionary, Wantink inherently teaches that the first polymeric material has a higher glass transition temperature (Tg) than the second polymeric material forming the distal portion of the proximal tubular member.

However, Wantink discloses that the proximal tubular member 26 is formed of a high strength material such as a 304 stainless steel or NiTi alloy hypotubing (see column 4, lines 4-6). Therefore, contrary to the Examiner's assertion, Wantink does not inherently teach that the reinforcing member 28 is formed of a first polymeric material necessarily having a higher Tg than the distal portion of the proximal tubular member 26, because Wantink explicitly discloses that the proximal tubular member 26 may be formed of a metallic material. Moreover, even if proximal tubular member 26 of Wantink was formed of a polymeric material, a reinforcing member might function as a reinforcing structure merely by increasing the wall thickness of the shaft, irrespective of the Tg of the reinforcing member polymeric material.

The Examiner rejected claims 1-5, 9, 23-33, 35 and 37-39 under 35 USC §103(a) as being unpatentable over Verbeek in view of Samson et al., stating that Verbeek discloses the claimed invention except for using a thermoset polyimide, and Samson et al. discloses the use of a thermoset polyimide with a reinforcing structure in a catheter. However, as discussed above, Verbeek does not inherently disclose or suggest a reinforcing member having a higher Tg than the distal portion of the proximal tubular member.

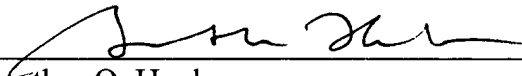
Applicants wish to bring to the attention of the Patent Office the references listed on the attached Form PTO/SB/08A and request that they be considered by the Examiner. This Information Disclosure Statement is being submitted pursuant to 37 CFR 1.97(c)(2), and therefore the fee under 1.17(p) is due.

In light of the above amendments and remarks, applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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